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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PERTTI TÖRMÄLÄ, MINNA KELLOMAKI, WILLIAM BONFIELD, and KATHLEEN E. TANNER

Appeal 2008-2657
Application 08/921,533
Technology Center 1600

Decided: May, 27, 2008

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a biodegradable and bioactive composite material which the Examiner has rejected under the judicially created doctrine of obviousness type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part and reverse in part.

Background

"In surgery, either biostable or biodegradable devices are used for the fixation of bone fractures to immobilize the bone fragments and accelerate patient mobilization" (Spec. 1). The Specification notes that "[m]ost biostable devices are typically made of metallic alloys" (Spec. 1). According to the Specification, "[b]ioresorbable polymeric fracture fixation devices have been studied as replacements for metallic implants" (Spec. 2). "Törmälä et al. have developed self-reinforced bioresorbable polymeric composites to improve the strength of bioresorbable polymer devices. These show good mechanical properties: e.g. bending strengths of 360±70 MPa and bending moduli of 12±2 GPa, respectively, have been reported" (Spec. 2).

Statement of the Case

The Claims

Claims 1-6 and 9-22 are on appeal. We will focus on claim 1, which is representative and reads as follows:

> 1. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component and iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component, wherein the bioceramic or bioglass reinforcing component has a particle size of is [sic] between 60 μm and 150 μm.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Törmälä	US 4,743,257	May 10, 1988
Bajpai	US 4,778,471	Oct. 18, 1988
Törmälä	US 6,406,498 B1	Jun. 18, 2002

The issue

The rejection as presented by the Examiner is as follows:

Claims 1-6 and 9-22 stand rejected under the judicially created doctrine of obviousness-type double patenting as obvious over claims 1-10 of Törmälä '498 in view of Törmälä '257 and Bajpai (Ans. 3).

Obviousness type double patenting rejection

The Examiner argues that

> [a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because '498 teach bioactive, bioabsorbable surgical composite material comprising a bioabsorbable polymer matrix that is oriented and bioactive glass or ceramic particles dispersed in the matrix that is self-reinforced, wherein said particles extend at least into said pores.

(Ans. 3.) The Examiner also notes that "'498 claims particle sizes but fails to claim the specific particle size of 60 to 150 microns" (Ans. 3). The Examiner relies upon Törmälä '257 to "teach mixing together a melt of the absorbable polymer or copolymer and subjecting to heat and pressure (examples and claim 12)" (Ans. 4). The Examiner relies upon Bajpai to "teach particulate ceramic materials that have particle size of about 1 to 400 microns. '471 teach that for a bone implant device, a particle size of 40 to 200 microns can be used" (Ans. 4).

Appellants argue that "there is no motivation to combine the '471 patent with the claims of the '498 patent" (App. Br. 5). Appellants contend that the Törmälä '498 patent claims "are clearly directed to a surgical composite material that comprises a polymer matrix that has bioactive glass or ceramic dispersed therein. The '471 patent, on the other hand, is directed to a ceramic used as a drug delivery system, cement or grout or a preformed implant or ceramic block" (App. Br. 5). Appellants conclude that "[t]here is no suggestion that the powdered ceramic described in the '471 patent should be dispersed in any way in other material to form a composite material" (App. Br. 5).

Appellants also argue that "the claimed particle size of 60 μm to 150 μm of the bioglass or bioceramic reinforcing component is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue compared to particle sizes taught in the art" (App. Br. 6).

In view of these conflicting positions, we frame the obviousness-type double patenting issues before us as follows:

(1) Would it have been obvious to a person of ordinary skill to select particles from 60 μm to 150 μm from Bajpai as reinforcing the polymer matrix of claims 1-10 of Törmälä '498?

(2) Does the evidence support a conclusion of a secondary consideration of unexpected results for the specific particle sizes claimed?

Findings of Fact

1. Törmälä '498, claim 1 teaches

[a] bioactive, bioabsorbable surgical composite material comprising: a bioabsorbable polymer matrix which is

> oriented, said matrix having an outer surface and containing a plurality of pores, wherein at least some of said pores open at the surface of said matrix; and bioabsorbable or bioactive particles dispersed into the polymer matrix, said particles being comprised of glass or ceramic, wherein said particles extend at least partially into said pores.

(Törmälä '498 16:45-54, claim 1).

2. Törmälä '498, claim 5 teaches "[a] composite material according to claim 1, wherein said matrix is self-reinforced" (Törmälä '498 16:64-65).

3. Törmälä '498 discloses the use of particles of 50-125 μm in the manufacturing method in the Specification (Törmälä '498, 8:43).

4. Bajpai teaches the use of zinc ceramics as implants with the "implant being essentially non-toxic and bioabsorbable" (Bajpai 2:30-31; 1: 5-7).

5. Bajpai states that the ceramic can be in powder form where the "particle size of the bioceramic varies with the end use" (Bajpai 3:10-11). Bajpai teaches that where the ceramic is used for cement or grout, "the ceramic has a particle size of about 1 to 400 microns" (Bajpai 3:13-14). However, Bajpai teaches that where the ceramic is used "[f]or a bone implant device, the ceramic has a particle size of about 40 to 200 microns" (Bajpai 3:14-16).

6. Törmälä '257 teaches an osteosynthesis material that "is self-reinforced, i.e. it is formed of an absorbable polymer or copolymer matrix which is reinforced with absorbable reinforcement which have the same chemical element percentage composition as does the matrix" (Törmälä '257 3:8-12).

7. Törmälä '257 teaches "methods which can be applied in manufacturing of self-reinforced absorbable osteosynthesis materials" (Törmälä '257 4:1-3).

8. Törmälä '257 teaches manufacturing reinforced osteosynthesis materials by

(a) Selecting an "absorbable polymer" (Törmälä '257 4:19),

(d) Selecting a second polymer of "fibers, threads or corresponding reinforcement elements of the same material" (Törmälä '257 4:19-20),

(e), (f) "forming the mixture of the polymer melt and reinforcement elements into the desired form" (Törmälä '257 4:20-22),

(g) "cooling the formed polymers composite so rapidly that the reinforcement elements do not significantly lose their oriented internal structure" (Törmälä '257 4:22-25).

9. Törmälä '257 teaches fibers for self reinforcement with a variety of diameters (Törmälä '257 6:30-60). Specifically, Törmälä '257 teaches "[p]oly-β-hydroxybutyric acid (M_w=80,000) fibers (diameter 15 μm)" (Törmälä '257 6:54-55). Törmälä '257 also discloses fibers with diameters of 6 μm (Törmälä '257 7:23) and 12 μm (Törmälä '257 6:42-43).

Discussion of the Obviousness type double patenting rejection

Claim 1

We conclude that the Examiner has set forth a prima facie case that claim 1 is obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai. Claim 1 of Törmälä '498 teaches bioabsorbable composite materials which comprise a "bioabsorbable polymer matrix" and a bioglass or bioceramic reinforcing component (FF 1) as in instant claim 1. Törmälä

'257 teaches the use of a polymeric self reinforcement material which is absorbable (FF 6). Bajpai teaches the use of bioceramic particles in implants with a particle size between 40 and 200 microns (FF 4-5). Based on these teachings, we agree with the Examiner that

> it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bioglass or ceramic particles, in an appropriate particle size range in the surgical composite material of '498 depending on the use of ceramic particles as a cement or for drug delivery, because '471 suggests specific particle sizes for either purposes (cement or drug delivery) and suggests that increase in particle size is associated with a decrease in mechanical strength and an increase in porosity.

(Ans. 4-5.)

We are not persuaded by Appellants' argument that "there is no motivation to combine the '471 patent with the claims of the '498 patent" (App. Br. 5). Both Törmälä '498 and Bajpai are concerned with bioabsorbable implants (FF 1, 5) and Bajpai teaches the use of ceramic particles in the size range of 40 to 200 microns when making bone implants (FF 4). Bajpai provides specific motivation to use resorbable zinc ceramic particles of the claimed size in implants, teaching that "an object of the present invention is to replace the aluminum oxide in aluminum based ceramics with zinc oxide to provide a ceramic having the properties of an aluminum based ceramic and which is resorbable but without the potential toxic side effects of aluminum" (Bajpai 2:3-8).

We are also not persuaded by Appellants' argument that "[t]here is no suggestion that the powdered ceramic described in the '471 patent should be dispersed in any way in other material to form a composite material" (App.

Br. 5). Claim 1 of Törmälä '498 expressly teaches the use of ceramic materials "dispersed into the polymer matrix" of the composite material (FF 1), and Bajpai teaches that the zinc ceramic particles are useful in bone implants (FF 4). In *KSR*, the Supreme Court stated that "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). In the instant case, selection of Bajpai's ceramic particles used to form bone implants for use in the composite surgical implant material of claim 1 of Törmälä '498 is a predictable variation, particularly since claim 1 of Törmälä '498 expressly teaches the use of ceramic particles (FF 1) and Bajpai teaches a ceramic particle which is useful in implantable materials.

Appellants argue that there are unexpected results regarding the particle size. Appellants contend that coarser particles, of 80 +/- 20 microns show greater biocompatibility than finer particles of 7.43 microns (*see* App. Br. 6). Appellants present evidence to support this contention in Example 11 of the Specification (Spec. 13:8-23).

We reject Appellants argument because evidence of unexpected results must be compared to the closest prior art. *See In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)("an applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art.") In this case, the closest prior art ranges for the particle sizes would have been the 40 to 200 micron particle size range disclosed by Bajpai (FF 4). In either case, the lower range point selected by

Appellants of 7.43 microns, did not fall within the ranges disclosed by the prior art as useful in bone implants (*see* FF 3-4). Therefore, "appellants' assertions of unexpected results constitute mere argument and conclusory statements in the specification which cannot establish patentability." *In re De Blauwe*, 736 F.2d at 705.

We therefore affirm the obviousness type double patenting rejection of claim 1 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai. Claims 5, 6 and 11-13 fall with claim 1 as they were not separately argued.

Claims 2, 17, 18, 19, and 20

Appellants' argue that the "'498 patent recites no method of manufacturing a biodegradable composite. The '257 patent makes no mention of a bioceramic or bioglass reinforcing component. Therefore, steps (c) and (f) of claim 2 are not disclosed by the combination of the '257 patent and the '498 claims" (App. Br. 7).

We find that Törmälä '257 teaches the entire manufacturing method (FF 8) except for the incorporation of ceramic particles into the first polymer as required by elements b) and c) of the claims. However, claim 1 of Törmälä '498 expressly requires that the composite material incorporate glass or ceramic particles (FF 1) and Bajpai teaches ceramic particles for use in bone implants (FF 4). We conclude that the express teaching by claim 1 of Törmälä '498 to incorporate glass or ceramic particles into the matrix would have suggested performance of the selecting step (b) and mixing step (c) in order to disperse the particles as required by claim 1 of Törmälä '498.

Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR*, 1727 S. Ct. at 1740.

We therefore affirm the obviousness type double patenting rejection of claim 2 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai. Claims 17-20 fall with claim 2 as they were not separately argued.

Claims 3, 4 and 16

Appellants argue regarding claim 3 that the prior does not teach a "reinforcing component has a fiber diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component" (App. Br. 8). The Examiner responds that the Törmälä '257 teaches fibers with diameters of "4.5 mm, 4.9 mm etc (see examples of '257), which are much greater than the particle sizes described by '471" (Ans. 8).

The fiber diameters in Törmälä '257 of 4.5 mm referenced by the Examiner refer to the completed mixture and not to the individual fibers within the mixture (*see* Törmälä '257 5:30-35, "The melt-fiber mixture was formed rapidly to cylindrical samples (diameter 4.5 mm)"). When Törmälä '257 does discuss fibers in the mixture, the diameters are much smaller, with a diameter of 12 μm for the poly-L-lactide fibers and 15 μm for the poly-B-hydroxybutyric acid fibers (*see* Törmälä '257 6:42-43, 6:54-55). These fiber diameters are smaller than the particle diameters suggested by Törmälä '257 for use in implants (FF 4).

We agree with Appellants that since Törmälä '257 does not teach fibers with larger diameters than the reinforcing particles it would not have been obvious to have a fiber diameter greater than the diameter of the particle reinforcing component as required by claims 3, 4, and 16.

We reverse the obviousness type double patenting rejection of claims 3, 4, and 16 as obvious over claims 1-10 of Törmälä '498 in view of Törmälä '257 and Bajpai.

Claims 9 and 10

Appellants argue regarding claims 9 and 10 that the prior art does not teach that an "amount of the bioceramic or bioglass reinforcing component is 0.15 to 0.9 and 0.2 to 0.6 volume fraction" (App. Br. 9). Appellants argue that the "'498 patent claims simply provide no guidance to any particular amount range for the claimed bioabsorbable or bioactive particle. Moreover, the Examiner has pointed to no teaching that indicates that the amount of bioglass or bioceramic reinforcing component is a result-effective variable" (App. Br. 9). The Examiner responds to this argument that "optimizing the volume of ceramic particles in the implant or composite material of '498 would have been within the scope of a skilled artisan" (Ans. 8).

In *KSR*, the Supreme Court noted that "the [obviousness] analysis need not seek out precise teachings directed to the subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ". *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007). Here, when Törmälä '257 teaches to incorporate reinforcement units into a surgical osteosynthesis material such as that taught in claims 1-10 of Törmälä '498 (FF 1-5), the person of ordinary skill would have recognized that the amounts of material being incorporated may be optimized to result in optimal strength of reinforcement. *See In re Boesch*, 617 F.2d 272, 276 (CCPA 1980).

("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.")

We therefore affirm the obviousness type double patenting rejection of claims 9 and 10 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai.

Claim 14

Appellants argue regarding claim 14 that the prior art does not "describe any specific types of bioactive glass or ceramic particles, let alone the specific types of particles recited by claim 14" (App. Br. 10). The Examiner responds that "the ceramic particles of '257 do[] read on the instant bioceramic materials and further, '257 does recognize hydroxyapatite as the conventional ceramic materials for drug delivery systems" (Ans. 8).

We note that the Examiner also identified support for the use of hydroxyapatite in Bajpai (see Ans. 4), where Bajpai recognized that hydroxyapatite is an equivalent material for use in the same applications as the ceramics (see Bajpai, col. 1, ll. 63-67). Such a substitution of a known material is merely a "predictable use of prior art elements according to their established functions." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

We affirm the obviousness type double patenting rejection of claim 14 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai.

Claim 15

Appellants argue that the prior art does not teach that "the composite material exhibits ductile behavior under load" (App. Br. 10). Appellants Specification does not define ductile, but does state that reinforcement

"changes the behavior of the material from brittle to ductile and thus makes the reinforced device more reliable under load" (Spec. 8:1-2).

We think that the teaching of Appellants own Specification cited above supports the conclusion that reinforcement of a material will make that material more ductile. Since both claims 1-10 of Törmälä '498 and the disclosure of Törmälä '257 expressly discuss reinforcement of the osteosynthesis materials with fibers and particles, it is necessarily the case that the composite materials of the prior art will show some level of ductility consistent with the admission of Appellants' Specification.

We therefore affirm the obviousness type double patenting rejection of claim 15 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai.

Claims 21 and 22

Appellants argue that the prior art does not teach "any particular fiber diameter, let alone the specific fiber diameter recited by claims 21 and 22" (App. Br. 11). In fact, Törmälä '257 teaches the use of fibers with diameters of 6 μm, 12 μm, and 15 μm (FF 9). These diameters fall within the range claimed by claim 21. While the fiber diameters in Törmälä '257 do not teach the minimum 20 μm required by claim 22, we think that in view of the closeness of the ranges, and the expectation that even larger diameters would work, an ordinary practitioner would have had the creativity to routinely optimize the fiber diameters. *See KSR* supra; *Titanium Metals Corp. of America v. Banner,* 778 F.2d 775, 783 (Fed. Cir. 1985).

We therefore affirm the obviousness type double patenting rejection of claims 21 and 22 as obvious over claims 1-10 of Törmälä '498, Törmälä '257 and Bajpai.

CONCLUSION

In summary, we affirm the rejection of claims 1, 2, 9, 10, 14, 15, 21 and 22 under the judicially created doctrine of obviousness type double patenting. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 5, 6, 11-13, and 17-20 as these claims were not argued separately. We reverse the rejections of claims 3, 4, and 16 under the judicially created doctrine of obviousness type double patenting.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED IN PART

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